

REMARKS

Claims 3-5, 9-12, 34, 39, 40, and 62 are pending in the application. Claims 6-8, 13-33, 35-38, 41-61, and 63-84 are cancelled. Claims 3 and 40 are amended. Claims 85-87 are new. No new matter has been added.

Objections to the Claims

The Examiner objects to claim 3 as allegedly containing a typographical error. However, claim 3 does not need to be re-numbered, but is correct as written. Withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

New matter

Claims 3-5, 9-12, 34, 39, and 62 are rejected as allegedly lacking an adequate written description. In support of the rejection, the Examiner asserts that Applicants claims do not recite all of the markers included in the Examples. Applicants respectfully disagree and traverse the rejection.

As indicated at page 4, second paragraph, Applicants clearly indicate that the method includes the use of the markers individually or in combination. Additional support is found in Applicants claims as filed, which indicate that the method involves the use of “one or more markers (e.g., claim 1). Accordingly, this basis for the rejection should be withdrawn.

Enablement

Claims 3-5, 9-12, 34, 39, and 62 are rejected as allegedly lacking enablement. In support of the rejection, the Examiner alleges that Applicants have failed to enable all sample types. The claims now specify “blood” sample. Accordingly, this basis for the rejection should be withdrawn.

In further support of the rejection, the Examiner questions (i) how the molecular weight was measured, and (ii) whether Applicants' examples show that the "average" peak value was used in the diagnostic method. The Examiner's concerns are addressed by the present amendment, which specifies that the protein's are analyzed using mass spectroscopy. Applicants note that this is supported in the Examples. Mass spectroscopy was used to obtain the protein profile (See, for example, Figure 1 and page 11, paragraph spanning lines 21-23, also page 12, lines 14-17).

With regard to whether an average measurement was used, Applicants specification makes clear, for example, at page 48, lines 4-6, that absolute levels of markers could be used to classify disease. Thus, it is not necessary to use average peak values.

In further support of the rejection, the Examiner alleges that it would be unpredictable whether the claimed methods would work to diagnose ovarian cancer. Applicants respectfully disagree.

The Office bears the initial burden of establishing a reasonable basis to question the enablement of the claimed invention. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). The Office must provide evidence showing why undue experimentation would be required to practice the claimed invention.

[I]t is incumbent upon the patent office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Applicants have shown that the claimed methods are plainly useful to classify subjects with regard to ovarian cancer. See, for example, page 48, lines 4-28, Figures 6-9, and Tables 1 and 2, which plainly show that the claimed methods can be used to diagnose ovarian cancer. In view of Applicants' disclosure, there is no reason to doubt that the methods would work as presently claimed.

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Dated: October 18, 2011

Respectfully submitted,
Electronic signature: /Melissa Hunter-Ensor,
Ph.D., Esq./
Melissa Hunter-Ensor, Ph.D., Esq.
Registration No.: 55,289
EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5580
Attorneys/Agents For Applicant